Remarks/Arguments

In his rejection of claims 1-17 dated December 8, 2003, the examiner has again relied on the admitted prior art system disclosed in the applicant's specification to form the basis of the Examiner's rejection for obviousness. The applicant had previously addressed any questions concerning this prior art system with the submission of an affidavit of Mr. Brian Dockendorff setting forth how the prior art system described in the specification had numerous drawbacks that were well known to those having skill in the art, and that the invention described and claimed in the instant patent application had overcome those drawbacks. In his rejection of March 27, 2003, the examiner disputed the conclusion drawn by this affidavit, and argued that the affidavit did not "present any data (e.g. comparative test data) form which a conclusion of superior results can be drawn." The applicant then submitted a second affidavit of Mr. Dockendorff, wherein Mr. Dockendorff expanded on his previous statements, providing the comparative data sought by the examiner. In his December 8, 2003 rejection, the examiner averred that this affidavit was still not sufficient to overcome the examiner's rejection. The examiner posited numerous hypothetical factors which the examiner asserted might account for the differences in performance between the two systems, e.g. differences in tolerances, differences in the materials of construction, and differences in the volume of fluid run through the systems. The examiner provided no evidence whatsoever that any of these factors had any effect whatsoever on the system's reliability, and despite Mr. Dockendorff's sworn statement that the reason for the failures is inherent in the design of these systems, the examiner again rejected the claims.

In response to the examiner's rejection, the applicant, Ms. Cynthia Bruckner-Lea, together with the undersigned and Mr. Dockendorff, met with the examiner on March 10, 2004, to discuss the examiner's basis for rejection. Mr. Dockendorff explained to the examiner that his prior affidavit did contain an "apples to apples" comparison, and further explained that all of the hypothetical factors for differences in failure rates set forth in the examiner's December 8, 2003 rejection were negligible when compared with the differences caused by the design of the systems. Mr. Dockendorff further explained that during his time working with the prior art

systems in Dr. Ruzika's laboratory, he, along with the other scientists, brainstormed to come up with an alternative design that would overcome the problems of the prior art systems, and were unable to do so. Despite this overwhelming evidence of non-obviousness, no agreement was reached with respect to patentability.

The applicant therefore submits a third affidavit by Mr. Dockendorff herewith. In this affidavit, Mr. Dockendorff again explains that he has extensive experience with solid rod type microfluidic systems and the rotating rod type microfluidic systems. Mr. Dockendorff further explains that in some of these cases, the materials of construction and tolerances were essentially identical, for example, a stainless steel rod was inserted into a Teflon block where the tolerance is designed to be as tight as possible, resulting in the two systems exhibiting, at least initially, essentially identical tolerances. Mr. Dockendorff notes that the failure rates for these identical systems were included in the results described in his August 21, 2003 affidavit, which demonstrated that in all cases, the rotating rod types microfluidic systems do not break down nearly as rapidly as the solid rod microfluidic systems.

Mr. Dockendorff explains that the reasons for these differences is a result of the fact that the solid rod microfluidic systems are operated by repeatedly inserting and removing the solid rod from the block, the hard edge at the end of the rod has a tendency to scrape away at the material forming the block, loosening the initial tolerance between the rod and the block, and eventually forming leaks between the rod and the block. Mr. Dockendorff explains that the beads used in both types of microfluidic systems have a tendency to facilitate this process, but that it is far worse in the solid rod type systems, as the piston-like motion of the solid rod systems allows the beads an opportunity to become wedged in between the rod and the block where it acts as an abrasive. The rotating rod microfluidic systems, due to their design, do not create this abrasive action between the hard edge at the end of the rod and the block. Only the smooth, curved surface along the length of the rod is moved against the block in the rotating rod systems, with only the tip of the rotating rod coming in contact with the particles. In the solid rod systems, there far more opportunity for the beads to come between the rod and the block, due to the repeated insertion and removal of the rod. As such, the use of some types of

beads, such as irregular shaped glass, is possible with the rotating rod type systems, whereas the use of irregular shaped glass will develop leaks in a solid rod system so rapidly that their use is not practical.

Mr. Dockendorff further explains that he has worked with systems that use different materials of construction. For example, systems that used a plexiglass block, and systems that have used a nickel rod. Mr. Dockendorff explains that in all cases, the results are the same. The solid rod systems have a tendency to quickly develop leaks and the rotating rod systems do not. Mr. Dockendorff explains that, based on his extensive first hand experience in working with each of these types of systems, the design is the only variable that has any appreciable effect on the development of leaks within the systems. All other variables, including bead types, materials of construction, flow rates, sample type, and tolerances, have no observable effect on the rate at which the rotating rod systems develop leaks. However, even if the optimal bead types, materials of construction, flow rates, sample type and tolerances are used in a solid rod system, the system will nevertheless develop leaks due to the design of these solid rod systems.

Mr. Dockendorff further states, for the record, that during his time in Professor Ruzicka's laboratory, where he was working exclusively with the solid rod type systems described in the background section of the specification of the above captioned patent application, the laboratory staff (himself included) were well aware of the drawbacks and disadvantages inherent in the prior art solid rod type systems, since they were tasked with the maintenance and repair of the systems. These drawbacks created significant incentives for them to create alternative systems that would overcome these drawbacks and disadvantages, and on more than one occasion they brainstormed among themselves in an attempt to devise a system that would solve the problems. Despite their efforts, to his knowledge, none among them, whom he would consider as having at least ordinary skill in the art, were ever able to conceive or reduce to practice any effective system for overcoming these disadvantages.

Mr. Dockendorff then concludes that the rotating rod concept described in the above captioned patent application was the first design that he is aware of that solved those problems, and in his opinion, the rotating rod concept described in the above captioned patent application was not obvious to any of those having ordinary skill in the art. The rotating rod system thus fulfilled a long felt need among those having ordinary skill in the art for alternative systems that would overcome the drawbacks and disadvantages inherent in the prior art solid rod systems.

Thus, the unambiguous and uncontroverted evidence before the Patent and Trademark Office now establishes that:

1) In direct comparisons, using the same materials of construction with the same tolerances, the solid rod systems of the admitted prior art rapidly develop leaks, and the rotating rod systems claimed by the applicant do not.
2) The differences in failure rates are a result of differences in the design of these systems, the same differences in design claimed by the applicant in the above captioned patent application, and all of the non-design factors posited by the examiner as accounting for these differences have a negligible effect on the relative failure rates.
3) The drawbacks and disadvantages inherent in the design of the prior art solid rod type systems created significant incentives for alternative systems that would overcome these drawbacks and disadvantages, and those having ordinary skill in the art were very aware of these incentives.
4) Despite the incentive for alternative systems that would overcome these drawbacks and disadvantages of these prior art solid rod systems, none among those having ordinary skill in the art were able to conceive or reduce to practice any effective system for overcoming these disadvantages, despite their best efforts, until the rotating rod concept described in the above captioned patent application was conceived.
5) Those having ordinary skill in the art recognize that the rotating rod concept described in the above captioned patent application fulfilled the long felt need for alternative

systems that overcome the drawbacks and disadvantages in the prior art solid rod systems.

In the face of this evidence, the Patent and Trademark Office cannot set forth a prima facie case for obviousness under 35 USC 103(a). At the core of any such prima facie case is the requirement that the combination proposed by the examiner be obvious to "one of ordinary skill in the art." In the instant case, there is no need to rely on a hypothetical person of "ordinary skill in the art," as Mr. Dockendorff provides a living example of such a person. Mr. Dockendorff's explanation that the combination claimed in the instant application was not obvious to either he or any of his colleagues who actively sought to address the problem solved by the claimed invention is thus definitive. Further, even if Mr. Dockendorff's opinion that the instant invention was not obvious is ignored, the fact that the instant invention has provided a solution to a long felt need by those having skill in the art is sufficient to establish patentability. As set forth by the Federal Circuit, "Evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decision-maker remains in doubt after reviewing the art." Stratoflex, Inc. v Aeroquip Corp., 713 F.2d 1530, 1538-40, 218 USPQ 871, 879 (Fed. Cir. 1983). The Affidavit of Mr. Dockendorff establishes exactly those secondary considerations; specifically the fact that the present invention overcame a known drawback in the prior art, thereby filling a known and existing need. Again, as stated by the Federal Circuit, "Thus when differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made." Continental Can co. USA v. Monsanto Co., 948 F.2d 1264, 20 USPQ 2d 1746, 1752 (Fed. Cir. 1991).

When taken together with the binding Federal Circuit precedent, Mr. Dockendorff's affidavit thus compels a finding of non-obviousness. Mr. Dockendorff's affidavit establishes

conclusively that the "objective indicia" of "filling an existing need" was met by the device described and claimed in the above captioned patent application. Mr. Dockendorff's affidavit establishes quantifiable comparisons between the prior art device and the present invention, and is now "the most probative and cogent evidence in the record" and establishes "that an invention appearing to have been obvious in light of the prior art was not."

Applicant has made an earnest attempt to place the above referenced application in condition for allowance and action toward that end is respectfully requested. If the not allowed, the applicant respectfully requests that the affidavit off Mr. Brian Dockendorff nevertheless be entered into the record. Should the Examiner have any further observations or comments, he is invited to contact the undersigned for resolution.

Respectfully submitted,

Douglas E. McKinley, Jr.
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The undersigned hereby certifies that the forgoing Preliminary Amendment dated March 26, 2004 in reply to the office action of December 8, 2003, together with a fee sheet (form PTO/SB/17 1 page), the affidavit of Brian Dockendorff (3 pages) and a return postcard are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to

Mail Stop Non Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on the date set forth below.

Hope C. Houck
Hope Houck

March 26, 2004
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Homan, et al.	Art Unit: 1724
Serial No: 09/177,902	Examiner: Ivars C. Cintins
Filed: 10/23/98	Paper No:
For: METHOD AND APPARATUS FOR PACKED COLUMN SEPARATIONS AND PURIFICATIONS	File No: E-1658
	Date: March 15, 2004

AFFIDAVIT

I, Brian Dockendorff, do hereby declare and state as follows:

On March 10, 2003, I attended a meeting with examiner Ivars Cintins at the United States patent and Trademark office to discuss the above referenced patent application. During that meeting, examiner Cintins expressed a concern that the differences in performance between the solid rod type microfluidic systems and the rotating rod type microfluidic systems I discussed in my affidavit of August 21, 2003 may have been caused by factors other than the design of these systems, such as the materials of construction or the tolerances of the systems. To address those concerns, I would like to offer the following observations:

As described in my August 21, 2003 affidavit, I have worked extensively with solid rod type microfluidic systems and the rotating rod type microfluidic systems for the past seven years. In some of these cases, the materials of construction and tolerances were essentially identical. For example, I have worked with both systems wherein a stainless steel rod was inserted into a Teflon block. In each of these systems, the tolerance is designed to be as tight as possible, resulting in the two systems exhibiting, at least initially, essentially identical tolerances.

The failure rates for these systems are included in the results described in my August 21, 2003 affidavit, which demonstrated that in all cases, the rotating rod types microfluidic systems do not break down nearly as rapidly as the solid rod microfluidic systems. The reason for this is fairly

straightforward. Since the solid rod microfluidic systems are operated by repeatedly inserting and removing the solid rod from the block, the hard edge at the end of the rod has a tendency to scrape away at the material forming the block, loosening the initial tolerance between the rod and the block, and eventually forming leaks between the rod and the block. The beads used in both types of microfluidic systems have a tendency to facilitate this process, as the piston-like motion of the solid rod systems allows the beads an opportunity to become wedged in between the rod and the block where it acts as an abrasive. The rotating rod microfluidic systems, due to their design, do not create this abrasive action between the hard edge at the end of the rod and the block. The smooth, curved surface along the length of the rod is moved against the block in the rotating rod systems, with only the tip of the rotating rod coming in contact with the particles. In the solid rod systems, there are more opportunities for the beads to come between the rod and the block, due to the repeated insertion and removal of the rod. For example, the use of some types of beads, such as irregular shaped glass, is possible with the rotating rod type systems, whereas the use of irregular shaped glass will develop leaks in a solid rod system so rapidly that their use is not practical.

I have also worked with systems that use different materials of construction. For example, I have worked with systems that used a plexiglass block, and I have worked with systems that have used a nickel rod. In all cases, the results are the same. The solid rod systems have a tendency to quickly develop leaks and the rotating rod systems do not. It is my observation, based on my extensive first hand experience in working with each of these types of systems, that the design is the only variable that has any appreciable effect on the development of leaks within the systems. All other variables, including bead types, materials of construction, flow rates, sample type, and tolerances, have no observable effect on the rate at which the rotating rod systems develop leaks. However, even if the optimal bead types, materials of construction, flow rates, sample type and tolerances are used in a solid rod system, the system will nevertheless develop leaks due to the design of these solid rod systems.

I would also state, for the record, that during my time in Professor Ruzicka's laboratory, where we were working exclusively with the solid rod type systems described in the background section of the specification of the above captioned patent application, the laboratory staff (myself included) were well aware of the drawbacks and disadvantages inherent in the prior art solid rod type systems, since we were tasked with the maintenance and repair of the systems. These drawbacks created

significant incentives for us to create alternative systems that would overcome these drawbacks and disadvantages, and on more than one occasion we brainstormed among ourselves in an attempt to devise a system that would solve the problems. Despite our efforts, to my knowledge, none among us, who I would consider as having at least ordinary skill in the art, were ever able to conceive or reduce to practice any effective system for overcoming these disadvantages.

The rotating rod concept described in the above captioned patent application was the first design that I am aware of that solved those problems, and in my opinion, the rotating rod concept described in the above captioned patent application was not obvious to any of those having ordinary skill in the art. The rotating rod system thus fulfilled a long felt need among those having ordinary skill in the art for alternative systems that would overcome the drawbacks and disadvantages inherent in the prior art solid rod systems.

Upon penalty of perjury, by affixing my signature below, I hereby declare that the forgoing is true on this 16th day of March, 2004.

Brian Dockendorff